SDA ENVIRONMENTAL LEGISLATION REPORT

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FEDERAL LEVEL

ENVIRONMENTAL PROTECTION AGENCY

Mutagenicity Risk Assessments

Proposed Guidelines

Guidelines for mutagencity risk assessments were issued by the Environmental Protection Agency for public comment (Federal Register, November 13, 1980, pp.74984-8, attached).

EPA has developed guidelines to be used in evaluating the risks associated with human exposure to chemical mutagens and has created the Reproductive Effects Assessment Group in its Office of Research and Development. This group will have the responsibility for oversight of the agency's risk assessment activities. The assessments will be carried out according to the guidelines, which will be applied in a two-step process: First, the mutagenicity of a chemical will be determined; and second, it will be determined whether the chemical reaches or affects the gonadal organs. The results of these evaluations will be combined with human exposure information to determine the extent of mutagenic risk.

According to the Environmental Protection Agency, at least 10% of all human disease is genetically related. Such diseases result from changes in the composition or arrangement of genes and chromosomes. Some of the chemicals that are being released into the environment have been shown to have mutagenic effects on test animals and are assumed to have a potential for causing genetic damage to the human population. Many of these chemicals are widely used in drugs, food additives, cosmetics, industrial compounds and pesticides.

Comments on the Guidelines should be submitted by February 11, 1981 to:

Reproductive Effects Assessment Group (RD-689)
Office of Health and Environmental Assessment
Environmental Protection Agency
401 M Street SW
Washington, D.C. 20460.

Environmental Protection Agency, Rm. F-124, 401 M St., SW., Washington, D.C. 20460, (202-426-223).

SUPPLEMENTARY INFORMATION: Flax does not compete well with weeds; weed infestations result in poor stands of flax by reducing germination and competing with the developing flax plants. Wild oats and foxtails are common weed pests of flax. According to the Applicants, these weeds are present in all areas where flax is produced, and due to heavy snowfall this past winter, heavy weed growth delayed planting and shortened the time for use of preplant herbicides.

Eptam, Avadex, Dalapon, Carbyne, MCP Amine and Bromoxynil are registered for selective weed control in flax. According to the Applicants, the registered alternative pesticides are either not effective or are not acceptable control methods for wild oats, wild buckwheat and foxtails for this season's wet conditions.

Minnesota reports that Kittson, Lake of the Woods, Marshall, Pennington, and Roseau Counties, where flax is a major crop, grow from 75,000 to 95,000 acres of flax annually. Significant losses in agricultural income may be incurred, the Applicants claimed, if the exemptions were not granted.

North Dakota reports that Bottineau, Cavalier, Pierce, Pembina, Rollette, and Towner Counties annually grow about 98,000 acres of flax.

The Applicants proposed to use an asulam formulation, Asulox, EPA Reg. No. 359-662, in a single post-emergence application when wild oats are in the three- to four-leaf stage. Applications will be made by both private and commercial State-certified applicators using both ground and air equipment in Minnesota and ground equipment only in North Dakota in the counties named above.

EPA has determined that the available data are adequate to support the proposed use of Asulox on flax. Residues of the active ingredient (a.i.) asulam are not likely to exceed 2.0 parts per million (ppm) in flax seed and its fractions or 2.5 ppm in flax straw. EPA has deemed these levels to be adequate to protect the public health. Appropriate crop rotation restrictions have been imposed. No unreasonable adverse effect on the environment from this use of asulam is anticipated.

After reviewing the application and other available information, EPA has determined that the criteria for exemptions have been met. Accordingly, the Applicants have been granted specific exemptions to use the pesticide noted above until October 31, 1980, to the extent and in the manner set forth in the applications. The specific exemptions are also subject to the following conditions:

1. A single post-emergence application of Asulox (EPA Reg. No. 359-662) is authorized.

2. Application shall be made by air and/or ground equipment in Minnesota and by ground equipment in North Dakota, at a rate not to exceed 1.25 pounds a.i. per acre.

3. A maximum of 10,000 gallons of formulation may be applied to 32,000 acres of flax in the five Minnesota counties mentioned above; a maximum of 68,000 acres of flax in the six North Dakota counties named above may be treated.

4. Applications will be made when wild oats are in the 3-4 leaf stage.

5. All applications shall be made by State-certified private and commercial applicators.

6. Precautions shall be taken to avoid or minimize spray drift from target area. Application may not be made when weather conditions favor spray drift.

7. Residue levels of asulam are not expected to exceed 2.0 ppm in flaxseed and its fractions (meal, oilseed cake, refined oil, and soapstock) and 2.5 ppm in the flax straw. The Food and Drug Administration, U.S. Department of Health and Human Services, has been advised of these actions. Any resulting residues in meat, milk, poultry, and eggs will be well below detectable levels (0.05 ppm in meat, 0.025 ppm in milk, and 0.1 ppm in poultry tissues and eggs).

8. Crops other than small grains may not be planted in the treated area within 12 months of application. Small grain crops may not be planted within ten months of application. Root crops may not be planted in the treated area within 18 months of application. Fodder from grain crops rotated to treated flax fields may not be grazed or cut for forage.

9. All applicable directions, restrictions, and precautions on the EPA-registered label must be followed.

10. Application of Asulox to flax may result in crop injury and reduction in yield under stress conditions or if the herbicide is applied at stages of growth other than those specified.

11. The EPA shall be immediately informed of any adverse effects resulting from the use of Asulox in connection with these exemptions.

12. Each Applicant is responsible for ensuring that all of the provisions of its specific exemption are met and each must submit a report summarizing the results of this program by January 15, 1981.

(Sec. 18 as amended 92 Stat. 819; (7 U.S.C. 136))

Dated: November 6, 1980.

James M. Conlon,

Associate Deputy Assistant Administrator for Pesticide Programs.

[FR Doc. 80-35270 Filed 11-12-80; 8:45 am]

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[RP FRL 1563-2]

Mutagenicity Risk Assessments; Proposed Guidelines

October 30, 1980.

AGENCY: Environmental Protection Agency.

ACTION: Proposed guidelines for Mutagenicity Risk Assessments.

SUMMARY: The Environmental Protection Agency has developed Guidelines for Mutagenicity Risk Assessments (Guidelines). These Guidelines will be used within the policy and procedural framework provided by the various statutes which EPA administers, to guide Agency analysis of mutagenicity data.

These guidelines were developed by an Agency-wide working group, under the direction of the Reproductive Effects Assessment Group (REAG). REAC is an advisory body located within the Agency's Office of Research and Development, which serves as the senior Agency technical review group for mutagenicity assessment performed by Agency program offices. A preliminary draft of the Guidelines was sent for review to approximately 30 scientists in the field of chemical mutagenesis within government, universities in the United States and abroad, and the private sector. In general, the comments received were favorable, and changes in the draft were made, as appropriate, in response to them. In addition to soliciting public comments on the Guidelines by publication of this Federal Register Notice, the Agency is providing them to the Agency's Science Advisory Board for review.

FOR FURTHER INFORMATION CONTACT: Dr. Donna Kuroda, 202/426-2275.

DATES: Comments must be submitted by February 11, 1980.

ADDRESS: Reproductive Effects Assessment Group (RD-689), Office of Health and Environmental Assessment, Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

SUPPLEMENTAL INFORMATION:

I. Introduction

As a result of the progress in the control of infectious diseases, increase in average human lifespans, and better procedures for identifying genetic disorders, a considerable heritable

genetic disease burden has been recognized in the human population. It is estimated that at least 10% of all human disease is genetically related, resulting from changes in the composition or arrangement of genes and chromosomes (1, 2). Such genetic diseases can lead to structural or functional health impairments. Moreover, many of these diseases are expressed in infancy and in early childhood and are chronic in nature. As a result, they cause a severe impact upon the affected individuals and their families in terms of physical and mental suffering and economic losses, and upon society in general, which may often become responsible for institutional care. Some examples of genetic diseases and syndromes genetically based include Down's syndrome and Klinefelter's syndrome, cystic fibrosis, hemophilia, sickle cell anemia, and achondroplastic dwarfism. Other commonly recognized diseases which are likely to have a genetic basis include hypercholesterolemia, rheumatic fever, hypertension, pyloric stenosis, glaucoma, allergies, and several types of mental retardation. These diseases are only a few of the thousands which are associated with genetic errors (3).

Mutations are largely recognized as being deleterious to the organisms receiving them. The adverse effects may be manifested at the biochemical, cellular, and physiological levels of organization. Although mutations are the building blocks for further evolutionary change of species, it is believed that increases in the mutation rate above the spontaneous level will lead to an accumulation of deleterious mutations in the human population (4). Since the existing incidence of human genetic disease is already sizable, the Agency wants to control exposures to chemicals which may add to this existing burden.

Because of the technical and industrial expansion during the last two decades, a large number of chemicals have been released into our environment. Some have been shown to have mutagenic activity in mammalian and submammalian test systems, and thus have the potential to increase genetic damage in the human population. Chemicals with mutagenic activity in various test systems have been found widely distributed among drugs, food additives, cosmetics, industrial compounds, pesticides, and consumer products. As our knowledge of genetics and disease etiology increases, it is reasonable to believe that we will become aware of some chemically-induced human genetic effects. The extent to which exposure to these natural and man-made environmental agents may have increased the amount of genetic damage in the present human population and contributed to the mutational "load" that will be transmitted to future generations is unknown at this time. Since the prospect of curing most heritable diseases caused by mutagens in the near future is unlikely, minimizing exposure to mutagens is among the best available means to protect against further deterioration of the human gene pool.

This document describes the procedures that the Environmental Protection Agency (EPA) will follow to evaluate the risk associated with the exposure of humans to chemical mutagens. Previously, the Agency indicated its intent to develop procedures in the "Criteria for Evaluating the mutagenicity of chemicals" which describe the basic concerns and need for such a document (5). These procedures will ensure quality and consistency in the Agency's scientific risk assessments for mutagenic effects. The necessity for a consistent approach to evaluate the mutagenic risk from chemical substances arises from the authority conferred upon the Agency by a number of statutes to regulate potential mutagens. These statutes include the Federal Insecticide, Fungicide, and Rodenticide Act, the Toxic Substances Control Act, the Clean Air Act, the Federal Water Pollution Control Act, the Safe Drinking Water Act, and the Resource Conservation and Recovery Act.

The mutagenicity risk assessments prepared pursuant to these guidelines will be utilized within the requirements and constraints of the applicable statutes to arrive at regulatory decisions concerning mutagenicity. The standards of the applicable statutes and regulations may dictate that additonal considerations, e.g., the economic and social benefits associated with use of the chemical substance, will come into play in reaching appropriate regulatory decisions.

In order to ensure the quality and consistency of the Agency's scientific risk assessments, EPA has created the Reproductive Effects Assessment Group (REAG) in its Office of Research and Development. This group will have the responsibility for carrying out an oversight function for the Agency's risk assessment activities to ensure consistent application of mutagenicity risk assessment procedures, as well as the responsibility to conduct mutagenicity risk assessments for program offices when deemed necessary. The REAG will utilize, as appropriate, expert consultants and advisors from various Federal agencie academia, and the private sector to assist in reviewing mutagenicity risk assessments performed by the program offices or to assist REAG in performing risk analyses at the request of the program offices.

The assessment of heritable mutagenic risk to humans involves a two-step process. First of all, the mutagenicity of the chemical must be determined, and secondly, evidence must be evaluated to determine if the chemical reaches or affects gonadal organs. Results from such an evaluation can be combined with expected human exposure information, when available, and the impact of the mutagenic risk for human populations can be estimated to the extent possible.

II. Concepts Relating to Heritable Mutagenic Risk

For the purposes of these guidelines, a mutagen is defined as a chemical substance or mixture of substances that can induce alterations in the DNA of either somatic or germinal cells of organisms. The Agency is concerned with the risk associated with both germ cell mutations and somatic mutations. Mutations carried in germ cells can be inherited by future generations and contribute to genetic disease, whereas mutations occurring in somatic cells may be implicated in the etiology of several disease states, including cancer (6,7). These guidelines, however, only concern genetic damage as it relates to germ cell mutations. The position on the use of mutagenicity test results in the assessment of carcinogenic risk has been described in the Agency's Interim Cancer Assessment Procedures (8).

The potential for mutagenic risk to germ cells can be identified on the basis of tests involving either germ or somatic cells. In the case of somatic cell tests, however, the quantitation of mutagenic risk depends on evidence that the chemical or its metabolites reaches or affects a critical target (DNA) in germinal tissue.

There are several mutagenic endpoints of concern to the Agency. These include point mutations (i.e., change in the base sequence of DNA) and structural and numerical chromosome aberrations. Structural aberrations include deficiencies, duplications, inversions, and translocations, whereas numerical aberrations refer to gains or losses of whole chromosomes (aneuploidy) or sets of chromosomes (haploidy, polyploidy). The Agency's Office of Pesticide Programs already has

published various testing standards for the detection of mutagenic effects (9).

For some mutagenic mechanisms, it is conceivable that only one or a few molecules of the active compound may cause heritable changes in DNA. Mutagenic effects may also arise by mechanisms not directly related to chemical alterations of DNA, such as interference with DNA synthesis, DNA repair, or nuclear division processes.

III. Rationale for Using Nonhuman Test Systems

The virtual universality of DNA as the genetic material and of the genetic code provides a rationale for using various non-human test systems to predict the intrinsic mutagenicity of test chemicals. Additional support is provided by the observation that chemicals causing genetic effects in one species or test system frequently cause similar effects in other species or systems. Although cells of any species could theoretically be used to detect and predict genetic change in other species, certain test systems offer notable advantages, such as increased sensitivity; ease and speed of conducting the tests; low cost; anatomical, histological, and/or metabolic similarities to humans; suitability for handling large numbers of test organisms; a large data base; and a basis for characterizing genetic events.

Nonhuman test systems must be used because of the lack of suitable epidemiological data on germ cell mutations in humans. Clear epidemiological evidence for an increased mutation rate in humans due to exposure to a chemical substance is unavailable at this time. Presently only a very few of the estimated many thousands of genes in the human genome are useful as markers in determining the point mutation rates within human populations; there is a huge amount of genetic variability in the human population; and humans have a long generation time. Dominant and sex-linked recessive mutations can be detected in the first generation following treatment; however, autosomal recessive mutations and those affecting multifactorial traits largely go unnoticed because they are not recognized in the heterozygous state. Information on chromosomal aberrations induced in humans can be obtained with cytological techniques, but this information is limited. Thus, in most cases, although mutational changes occur in humans, they will be unobserved or unexpressed until future generations.

IV. Risk Assessment

A. Testing Systems

Assessing risks as a result of exposure to chemical mutagens is a complex task because of the diversity in chemical structure of mutagens and the various ways they can interfere with genetic processes. Therefore, in order to adequately assess the mutagenic potential of a chemical, data from several test systems may be needed to evaluate the ability of a chemical to produce chromosomal alterations, point mutations, and primary DNA damage (manifested by DNA repair or recombinational events). There are many testing systems currently available which can contribute information about the mutagenic potential of a test compound.

Test systems for detecting point mutations include those in bacteria, eukaryotic microorganisms, insects, and mammalian somatic cells in culture, as well as tests for detecting germinal mutations in intact mammals (e.g., the mouse specific locus test). Positive results in a mouse specific locus test argue strongly that a chemical is a potential human mutagen because the test demonstrates the mutation occurs in germinal cells and is transmitted to the next generation. However, since the development of mouse specific locus data is limited by the requirements for special strains of mice and a large number of test animals, it is not expected that many chemicals will be tested using this system. To obtain data on a large number of environmental pollutants, it will be necessary to rely on other tests to assess the risk of point mutations. Although prokaryotes, lower eukaryotes, and mammalian cells in culture do not have the ability to carry out all types of metabolic conversions that occur in intact mammals, the addition of a metabolic activation system derived from mammalian tissues has made these systems a valuable tool for detecting mutagens.

For detecting chromosomal aberrations, the following test systems have been employed: *in vitro* and *in vivo* mammalian cytogenetic tests, insect tests for heritable chromosome effects, dominant lethal tests in rodents, the heritable translocation test in rodents, and the mouse sex chromosome loss test. The heritable translocation test in rodents is among the best available tests for detecting heritable chromosomal rearrangements in mammals; the mouse X-chromosome loss test is a value in detecting the unequal distribution of chromosomal material during gametogenesis.

Other tests have been designed to detect nondisjunction (unequal distribution of chromosomes during cell division) in such diverse systems as the mouse, *Drosophila*, fungi, and mammalian cells in culture. The present data base for these systems, however, is limited at this time. Primary DNA damage which provides information bearing on the mutagenicity of a chemical can also be detected by a variety of test systems, such as unscheduled DNA repair synthesis in mammalian cells, mitotic recombination in yeast, and sister-chromatid exchange in mammalian somatic and germ cells.

The test systems mentioned above are not necessarily the only test systems that will provide the best evidence of mutagenicity. These systems are enumerated merely to demonstrate the breadth of the available techiques for assessing mutagenic potential, and to indicate the types of data which the Agency will consider in its evaluation of mutagenic potential. Most systems possess certain limitations which must be taken into account. The selection and performance of appropriate tests for evaluating the risks associated with human exposure to any suspected mutagen will depend on sound scientific judgment and experience, and may necessitate consultation with geneticists familiar with the sensitivity and experimental design of the test system in question. In view of the rapid advances in test methodology, the Agency expects that more relevant tools for predicting human mutagenic potential will become available with time. The Agency will closely monitor developments in mutagenicity evaluation and will refine its risk assessment scheme as better test systems become available.

B. Weight-of-Evidence Approach

The judgment as to whether a chemical substance is likely to be a potential human mutagen will be based on a weight-of-evidence approach that involves and considers the quality and adequacy of all the available data.

A positive response in the mouse specific locus test alone can provide strong evidence to regard a chemical as a potential human mutagen. As an alternative to the mouse specific locus test, positive responses in any two different point mutation test systems plus evidence for the presence of the test substance and/or its metabolites in mammalian gonadal organs also provides strong evidence that a compound is a potential human mutagen. Positive results in at least two systems are desirable because of the

possibility of obtaining false positive or species-specific positives.

The heritable translocation test or the X chromosome loss test for chromosomal alterations in mice can provide equally strong evidence that a chemical is a potential human mutagen. Both tests detect events that are induced in treated mammals and transmitted to progeny where they are scored. In the absence of positive findings in these two test systems, positive results in two *in vivo* somatic cell cytogenetic test systems or in an *in vitro* cytogenetic test system and an *in vivo* somatic cell cytogenetic test system, coupled with evidence for the presence of the test substance and/or its metabolites in mammalian gonadal organs, will provide strong evidence that a compound is a potential human mutagen.

The test systems described here may not detect all the genetic events that are of concern to humans. Furthermore, the sensitivity of some of these systems to detect mutations is not known and may be low for certain chemical classes. Nevertheless, positive responses in these tests currently provide the best experimental evidence that a chemical has the potential to produce genetic damage in people.

If data suitable for applying the criteria just described are not available, then the chemical substance under consideration will be assessed by examining all data that give insight to its mutagenic activity. The following factors will be considered:

1. Genetic endpoints (e.g., point mutations, chromosomal mutations) detected by the test systems.

2. Sensitivity and predictive value of the test systems for various classes of chemical compounds.

3. Number of different test systems used for detecting each genetic endpoint.

4. Consistency of the results obtained in different test systems and different species.

5. Whether the tests are conducted in accordance with appropriate test protocols agreed upon by experts in the field.

6. Evidence that a chemical reaches or affects the germinal tissue, as provided by such sources as data demonstrating the alkylation of DNA or other cellular macromolecules, unscheduled DNA synthesis, sister chromatid exchange, or chromosome aberrations, in germinal cells; and non-specific accumulation of radioactive label in the gonads following administration of the labeled chemical. Other relevant evidence includes adverse gonadal effects following acute, subchronic or chronic toxicity testing; and adverse reproductive effects, such as decreased fertilization index, reduced sperm count, or abnormal sperm morphology.

Data on these factors will be used to determine whether there is strong, substantial, or only suggestive evidence that a particular chemical may be potentially mutagenic to humans.

Although definitive proof of non-mutagenicity is not possible, it seems appropriate that a chemical could be classified operationally as a non-mutagen if it gives a negative response in an adequate number of test systems that are together capable of detecting all genetic endpoints of concern, namely, point mutations, chromosomal effects, and primary DNA damage. Furthermore, if a chemical does not reach or affect gonadal organs, it can be considered not to cause heritable mutations. Stringent scientific criteria (e.g., adequate sample size, suitable experimental design, appropriate concentration range, proper controls, and adequate number of tests) should be required for acceptance of negative results to assure that the failure to detect genetic activity or the presence of the chemical in the gonadal tissue is not based on inadequacies of the test procedures.

C. Quantitative Assessment of Results

The degree of risk can be estimated by combining the preceding qualitative evaluation for mutagenicity with the potential for human exposure. When there is a lack of appropriate mutagenicity data to make a quantitative estimate, risk can still be expressed in meaningful descriptive terms. To do this, the strength of evidence that the agent possesses intrinsic mutagenic activity, that it reaches or affects gonadal organs, and the extent and pattern of human exposure to the chemical, must be examined. From these elements a judgment as to the degree of human risk may be derived. When appropriate mutagenicity data are available for making a quantitative estimate of genetic risk to humans, two major approaches are available. One approach uses only experimental data on germinal alterations induced in intact mammals. Test systems providing such data are the heritable translocation, X-chromosome loss, and specific locus tests. These tests are complete in that they directly measure genetic damage in germ cells which is observed in a subsequent generation. In this approach, information on the level of human exposure is used with experimental data on induced mutation frequency, usually obtained at much higher exposure levels. An estimate of human risk is obtained by extra polating the induced mutation frequency downward to the approximate level of anticipated human exposure. With point mutational effects, there is a strong theoretical basis for the use of the linear or no-threshold models for this extrapolation (10, 11, 12). For certain chromosomal alterations, the biological mechanisms are generally thought to fit a multiple-hit model. Other mathematical models for extrapolation should, therefore, be considered when the dose-response data are able to fit an appropriate model. Linear extrapolation of the experimental data on translocations, for example, are likely to overestimate the risks present at lower levels of exposure and a model other than the one-hit model should be considered.

The other experimental approach for assessing genetic risk uses biochemical data from intact mammals and mutagenicity data from validated test systems (13, 14, 15). The intact mammal is used primarily for relating the exposure level for a chemical to germ cell dose. This involves relating the level of mutagen-DNA interactions in germ cells to the specific exposure level by an appropriate route of administration. This information is then used with results obtained from mutagenicity test systems in which the relationship between the induction of mutations and interactions with DNA can be made. Using mutagen-DNA interactions as the common denominator, a relationship can be constructed between exposure and the induced mutation frequency. In some cases, measurements of DNA binding induced by a particular chemical agent can be determined at levels of exposures which may affect human populations, and potential human risk can be determined without the extrapolation of the data to lower levels. Such results would not require a high to low exposure level extrapolation to determine potential human risk. In those instances where the lowest experimental exposure level is greatly above those levels to which humans are exposed, it will be assumed that DNA binding is directly proportional to the exposure level unless there are compelling reasons to believe otherwise.

For some mutagenic events, DNA may not necessarily be the critical target. Interaction of chemicals with other macromolecules, such as tubulin which is involved in the separation of chromosomes during nuclear division, can lead to chromosomal nondisjunction. At present the means are not available to make strictly quantitative assessments for these types of mutagenic mechanisms. Ongoing research should provide the means to

make future quantitative risk assessments for mutagens acting through these mechanisms.

In performing mutagenicity risk assessments, it is important to account for the sensitivity of the tests in detecting specific mutagenic endpoints. For example, although chemical substances which interact with DNA are likely to cause both point and chromosomal mutations, it is expected that point mutations may be relatively more frequent than chromosomal mutations at lower exposure levels. The former event can be initiated by a single interaction with DNA, whereas the latter may involve more than one interaction. Therefore, when assessing the mutagenic risk associated with low human exposures to the chemical, the point mutation data would generally be the more sensitive and appropriate information source.

Any risk assessment should clearly delineate the strengths and weakness of assumptions made, the uncertainties in the methodology, and the rationale used in reaching the conclusion, e.g., similar or different routes of exposure, metabolic difference between humans and test animals. The results should be expressed in terms of the excess of genetic disease per year or per lifetime, or the fractional increase in the assumed background spontaneous mutation rate of humans, or the radiation equivalency.

VI. References

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Dated: November 4, 1980.

Douglas M. Costle,

Administrator.

[FR Doc. 80-34958 Filed 11-12-80; 8:45 am]

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[OPP-180523; PH-FRL 1668-2]

New York; Issuance of Specific Exemption for Fenvalerate on Cabbage

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted a specific exemption to the New York Department of Environmental Protection (hereinafter referred to as the "Applicant") to use fenvalerate (Pydrin) on 12,000 acres of cabbage in New York to control the cabbage looper. The specific exemption is issued under the Federal Insecticide, Fungicide, and Rodenticide Act.

DATE: The specific exemption expires on November 1, 1980.

FOR FURTHER INFORMATION CONTACT: Libby Welch, Registration Division (TS-767), Office of Pesticide Programs, Environmental Protection Agency, Rm. E-124, 401 M St., SW., Washington, D.C. 20460, (202-426-0223).

SUPPLEMENTARY INFORMATION: The Applicant anticipates that an emergency situation will develop with respect to cabbage loopers on cabbage in upstate counties of New York. The Applicant contends that if the cool weather sets in during the last 35 days of cabbage growth, the cabbage looper will not be controllable. The Applicant claims that use of the pesticides registered for control of the cabbage looper is not practicable because:

1. The pesticide Phosdrin is not very effective against the pest and its residual action is short.

2. The pesticide Diazinon has not been effective in New York for many years.

3. Methomyl and *Bacillus thuringiensis* do not control the cabbage looper when temperatures are low.

4. While Monitor generally controls the pest, it may not be used within 35 days of harvest. This 35-day preharvest interval is a critical period for cabbage due to the unusually high infestation of the cabbage looper.

The Applicant estimates that the cabbage industry in New York could lose up to $12 million without adequate control.

The Applicant proposes to use fenvalerate at a rate of 0.1 to 0.2 pounds active ingredient (a.i.) per acre on up to 12,000 acres of cabbage. More than 50 percent of the fields checked in a county would have to be infested with cabbage loopers in numbers greater than one to two loopers per plant, as determined by research on Cooperative Extension personnel. Application would be made only when anticipated average daily temperature during the spray period is below 8° F during the day and/or 55–60° F at night.

EPA has determined that residues of fenvalerate in or cabbage should not exceed 2 parts per million (ppm) from the proposed use. EPA has judged this level to be adequate to protect the public health. No unreasonable hazard to the environment is anticipated from this program. Since fenvalerate is highly toxic to aquatic vertebrates and invertebrates and to bees, appropriate conditions to protect them having been imposed.

After reviewing the application and other available information, EPA has determined that the criteria for an exemption have been met. Accordingly, the Applicant has been granted a specific exemption to use the pesticide

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TO: DESIGNATED CONTACTS

FROM: AIHC

DATE: FEB. 3, 1981

CONTACT: Charles Osolin
Office of Public Information
202/395-5770

HOLD FOR RELEASE
Monday, January 19, 1981
6:00 PM E.S.T.

WASHINGTON -- Despite growing evidence linking certain chemicals with reproductive impairment in humans, few of the 55,000 chemical substances and mixtures now in commercial production have been tested for their effects on reproduction, according to a report released today by the President's Council on Environmental Quality (CEQ).

The report, Chemical Hazards to Human Reproduction, was prepared for CEQ by Clement Associates, Inc., a scientific regulatory consulting firm in Washington. The report identified a large number of factors that affect reproductive health, including drugs, chemicals, cigarettes, and alcoholic beverages.

According to Dr. Robert Harris, a member of the Council, "reproductive impairments, including the inability to conceive, miscarriages, premature births, low birth weight, birth defects and perinatal mortality are both frequent and widespread in the U.S. population, affecting millions of couples at one time or another.

"This report," Harris said, "clearly documents that environmental factors, such as nutrition, diet, stress, infections, and exposure to both natural and manmade chemicals are substantial contributors to certain types of reproductive impairment."

The report noted that although there is growing evidence linking chemical exposures in the workplace with reproductive failure, few efforts have been made to determine the significance of low-level chronic exposures to these chemicals by the public at large. Cigarettes and alcohol were the only agents reported to have shown substantial effects on the general population.

From a preliminary analysis of 21 chemicals that have been shown to represent a reproductive hazard to humans, the report concluded that laboratory studies on experimental animals correlate with the human effects from exposure to these chemicals. With one exception, humans appeared to be somewhat more sensitive to these chemicals than the most susceptible animal species tested.

Despite the availability of animal tests for assessing the potential reproductive hazards of chemicals, the report cautioned that there is no suitable pre-screening test for determining which among the thousands of chemicals to which humans are exposed are most in need of further animal testing to determine their reproductive hazard to humans. In contrast, a number of pre-screening tests are now in widespread use for determining the cancer-causing potential of chemicals before they are introduced to the marketplace.

Although the federal government has broad authority to regulate chemicals that pose reproductive hazards, the report concluded that regulatory agencies have placed relatively little emphasis on such hazards in their recent regulatory actions.

"This report argues both for greater attention to potential adverse reproductive effects in regulating chemicals," Harris said, "and for caution in developing such regulatory actions until better methods for risk estimation are developed."

The report also said current scientific knowledge of chemical hazards to reproduction is about where knowledge of cancer-causing chemicals was in the 1960s. "If scientific knowledge of reproductive hazards were developed in an orderly manner," the report said, "there would be an opportunity to avoid some of the controversies that have been raised by regulation of chemical carcinogens."

# # #

NOTE: Copies of Chemical Hazards to Human Reproduction are available from the Council on Environmental Quality, 722 Jackson Place, N.W., Washington, D.C. 20006. Please enclose a self-addressed mailing label and allow six weeks for delivery.

SDA GENERAL INFORMATION BULLETIN

Editor: Mary P. Kilcoyne

G-41

February 13, 1980

FEDERAL LEVEL

OCCUPATIONAL SAFETY AND HEALTH

Equal Employment Opportunity Commission

Interpretive Guidelines on
Employment Discrimination & Reproductive Hazards

The Equal Employment Opportunity Commission has proposed guidelines (Federal Register, February 1, 1980, pp.7514-7, attached) setting forth for the first time interpretations of the relationship between employment discrimination and the application of employer/contracter policies, practices and plans regarding reproductive hazards.

As proposed, the guidelines would regard personnel policies and practices which result in blanket exclusions of women as per se violations of both Title VII (of Civil Rights Act) and Executive Order No.11246, unless policies were justified by employers through research which studied the effect the workplace hazards have on men.

The proposed guidelines call "discriminatory" those "policies, practices or plans designed to protect employees from reproductive hazards which, by their terms, exclude applicants or employees from employment opportunities on the basis of sex". However, neutral policies which protect all employees from reproductive hazards are permitted if they do not have an actual "adverse impact" on only one sex.

The guidelines would require employers that currently have exclusion of women policies in existence to begin research to determine if men are affected by the hazardous substance. The research must be started within six months, and completed within two years, and may be conducted with OSHA or trade association assistance.

However, if an employer has already determined by "reputable scientific evidence" that men are not affected by the hazardous substance, but women are, the exclusionary policy may be continued, provided it is narrowly applied and alternative methods for placing female employees are explored. The guidelines would not permit "overboard policies", such as those which exclude all fertile women because of concern for possible harm to a fetus.

(continued)

The guidelines would permit "emergency temporary exclusion" in certain situations where the employer has reputable scientific evidence of workplace reproductive harm to one sex only, without such evidence of harm to the other sex. However, such temporary exclusions would have to be followed by research and investigation into suitable alternatives.

Comments are being solicited on the following:

(1) the nature and scope of exclusions from employment opportunities based on reproductive hazards in the workplace,

(2) the scientific evidence justifying or refuting the exclusion of sex-based classes,

(3) the provisions in the guidelines which allow the temporary emergency use of policies based on research on only one sex-based class,

(4) the requirements for balanced research, and

(5) the problem of tort or other liability of the employer/contractor because of compliance with proposed guidelines.

Such comments should be submitted by June 2, 1980 to:

Executive Secretariat
Equal Employment Opportunity Commission
2401 E Street, NW
Washington, D.C. 20506

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1603

DEPARTMENT OF LABOR

Office of Federal Contract Compliance Programs

41 CFR Part 60-20

Interpretive Guidelines on Employment Discrimination and Reproductive Hazards

AGENCY: Equal Employment Opportunity Commission and Department of Labor.

ACTION: Proposed rulemaking.

SUMMARY: This document sets forth for the first time proposed interpretations of the relationship between employment discrimination and the application of employer/contractor policies, practices and plans regarding reproductive hazards. The guidelines are intended to establish a consistent approach to enforcement of the legal responsibilities created under Title VII of the Civil Rights Act of 1964, as amended (Title VII), and Executive Order No. 11246, as amended (E.O. 11246). They are intended to provide guidance to the employer/contractor in meeting its responsibilities under Title VII and E.O. 11246 to ensure non-discrimination and to provide equal employment opportunity. These guidelines and the objectives of Title VII and E.O. 11246 are premised on the assumption that laws prohibiting discrimination in employment are consistent with those laws designed to assure a workplace free of conditions that threaten the health or safety of employees. It is recognized that the concerns of the enforcement agencies with respect to non-discrimination in employment are, however, distinct from the concerns of agencies responsible for health and safety regulation; these guidelines preserve those distinctions.

DATE: Written comments should be received by June 2, 1980.

ADDRESSES: Written comments may be addressed to: Executive Secretariat, Equal Employment Opportunity Commission, 2401 E Street, NW., Washington, D.C. 20506. All public comments may be reviewed from 9:30 a.m. to 4:30 p.m., Monday through Friday, at Library (Room 2303), Equal Employment Opportunity Commission, 2401 E Street, NW., Washington, D.C. 20506.

FOR FURTHER INFORMATION CONTACT: Frederick D. Dorsey, Director, Office of Policy Implementation, Equal Employment Opportunity Commission, 2401 E Street, NW., Washington, D.C. 20506, 202-634-7060, or James D. Henry, Associate Solicitor, Office of the Solicitor, Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20210, 202-523-6235.

SUPPLEMENTARY INFORMATION: An overview of the proposed Interpretive Guidelines on Employment Discrimination and Reproductive Hazards.

Introduction

These guidelines bring together the collective efforts and expertise of several federal agencies. These efforts were necessitated by charges presented to the Equal Employment Opportunity Commission (EEOC) and to the Office of Federal Contract Compliance Programs (OFCCP) (the enforcement agencies) alleging employment discrimination in workplaces containing substances and conditions hazardous to reproductive health. The issues addressed by these guidelines are especially important because employment policies, practices and plans relating to reproductive hazards can have the effect of denying employment opportunities to individuals.

In the course of its deliberations, EEOC, OFCCP and the Occupational Safety and Health Administration (OSHA) have had extensive discussions internally and with other federal agencies. The proposed guidelines clearly define the basic role of OSHA as one of consultation and coordination with EEOC and OFCCP, particularly with reference to scientific data. Sections 2(d)(2), 2(d)(8), 2(a)(3), 3(b)(1), and 3(c) of the proposed guidelines refer to the consultation and coordination that will be carried out, in part, through a Letter of Agreement among OSHA, EEOC and OFCCP.

It was also during this process that EEOC and OFCCP became aware of the increasing number of employers and contractors who are initiating policies excluding all women of childbearing capacity from certain jobs because of exposure to hazardous substances or conditions. Preliminary evidence indicates that as many as 20 million jobs may involve exposure in the workplace to alleged reproductive hazards. Chemicals and physical agents which have been alleged to pose such hazards include lead, polyvinyl chloride, radiation, estrogen, anesthetic gases, and organic solvents. In response to such exclusionary practices the EEOC, on April 21, 1978, issued a policy statement indicating its concern about whether such practices conform with federal anti-discrimination laws. In a May 31, 1978, letter from the Department of Labor's Assistant Secretary for Occupational Safety and Health John Bingham, to all major American corporate medical directors, OSHA expressed its concern regarding employment practices which deny opportunities to any class of workers on the basis of safety and health. These guidelines specifically address these situations involving allegations of sex discrimination.

EEOC and OFCCP have determined that policy guidance must be issued because, in the absence of detailed federal policy on this issue, there is widespread confusion among employers, contractors and the public as to what is required. Guidelines provide the most structured method for communicating policy to the public and also for ensuring public participation and input from all interested and affected parties. Consistent with the desire for extensive comments, this notice of proposed guidelines provides for a 120 day comment period.

The enforcement agencies are especially interested in obtaining comments on the following:

(1) the nature and scope of exclusions from employment opportunities based on reproductive hazards in the workplace,
(2) the scientific evidence underlying or refuting the exclusion of sex based classes,
(3) the provisions in the guidelines which allow the temporary emergency use of policies based on research on only one sex-based class,
(4) the requirements for balanced research, and
(5) the problem of tort or other liability of the employer/contractor because of compliance with proposed guidelines.

The enforcement agencies do not, at this point, see a need for a regulatory analysis. Comments on this are requested. The enforcement agencies especially note that the proposed guidelines do not attempt to implement or enforce federal policies related to health and safety. These guidelines affirm the goal of Title VII and E.O. 11246 to assure equality of employment opportunity. The task of assuring a workplace free of conditions that threaten the health or safety of employees remains with the federal agencies specifically granted that responsibility.

EXPLANATORY NOTE

Analysis

A number of employers and contractors have policies of not hiring women of childbearing capacity for jobs in which there is exposure to alleged

reproductive hazards and have terminated or transferred women to lower paying jobs based on such policies. Employers and contractors in establishing such practices often show a lack of concern for similar effects on men. Some employers and contractors have attempted to justify these policies on the basis of potential harm occurring to an unborn child through exposure of the mother. These policies have been developed without apparent regard to whether exposure of the father can result in harm to the unborn child.

Title VII and E.O. 11246 require that the enforcement agencies closely scrutinize the exclusion of a sex-based class from consideration for employment.

Section 2(a) reaffirms the unlawfulness of exclusions which by their terms are based on membership in a sex-based class. Such exclusions are *per se* violations of Title VII and E.O. 11246, because the exclusions are expressed or implemented in terms of membership in a class protected by Title VII and E.O. 11246.

Section 2(b) states that an employer/contractor's conduct which disparately treats members of a sex-based class raises a presumption of a violation of Title VII and E.O. 11246. Where such a presumption is raised, an employer/contractor will be given an opportunity to articulate a legitimate, non-discriminatory reason for the policy or practice. The enforcement agencies will then determine whether that reason is in fact a pretext for employment discrimination.

Section 2(c) is based upon the traditional concept of adverse impact. A facially neutral employment policy which has an adverse impact upon a specific sex-based class is an unlawful employment practice unless it is truly neutral (i.e., it is not a pretext for discrimination) [1] and is justified by the employer/contractor. [2]

It is important to note that, as a result of the Pregnancy Discrimination Act, Pub. L. 95–555, 92 Stat. 2077 (1978), women affected by pregnancy, childbirth or related medical conditions constitute a protected class under Title VII. All such women must be treated the same for employment-related purposes as other persons not so affected but similar in their ability or inability to work. For example, where an employer/contractor seeks to determine the hazardous reproductive effects on pregnant women from their exposure to a certain substance or condition, the employer/contractor must also determine the effects on males and non-pregnant females from their exposure.

If the hazard is known to affect the fetus through either parent, an exclusionary policy directed only at women would be unlawful under Title VII and E.O. 11246. Further, if the hazard is shown by reputable scientific evidence to affect the fetus through women only, the class excluded must be limited to pregnant women and not all women of childbearing capacity. Whether expressed in a policy or not, the employer/contractor's conduct will be examined by the enforcement agencies to determine whether the conduct is non-discriminatory or justified, as set out in section 2(d). In making this determination, at least the following factors, if relevant, will be considered. Whether:

1. the reproductive hazards policy has been applied consistently to both sexes;
2. the employer/contractor has complied with applicable occupational safety and health laws;
3. the employer/contractor has investigated the effects of all scientifically recognized reproductive hazards in its workplaces on those adversely affected and those not similarly affected;
4. the hazard is significantly greater for or confined to the excluded group;
5. the employer/contractor has a pattern of discrimination against the excluded group;
6. the policy is narrowly tailored to the type of hazard posed;
7. with respect to any reproductive hazard for which the employer/contractor takes action resulting in exclusion of a sex-based class, there is no evidence that the hazard poses a significant health risk to body systems other than the reproductive system for the class not excluded;
8. the employer/contractor has investigated alternatives to exclusion (in this regard it should be noted that the employer/contractor who is not in compliance with occupational safety and health laws relating to the hazardous substance or condition will be presumed to not have considered all available alternatives. This includes section 5(a)(1) of the Occupational Safety and Health Act, which requires an employer covered by the Act to furnish to each of its employees employment and a place of employment which are free from recognized hazards that are causing or likely to cause death or serious physical harm.);
9. the employer/contractor is monitoring scientific developments.

When justifying an exclusion or rebutting a presumption, the employer/contractor must demonstrate that the results of the research on which it relies are applicable to the circumstances in the employer/contractor's workplace where the substance is used or [illegible] the condition exists. This includes factors such as the level of exposure, manner of exposure, and the characteristics (including sex) of subjects studied—all compared to the substances use in the particular employer's workplace and the composition of the workforce in that workplace.

The enforcement agencies recognize that there may be situations where the employer/contractor has reputable scientific evidence of reproductive hazards to one sex-based class, only, but not evidence regarding the other sex-based class. These guidelines would not prohibit a temporary policy to protect the endangered sex-based class, provided that the policy (a) is narrowly tailored to those individuals for whom harm is indicated, (b) reflects consideration and adoption of less restrictive alternatives, and (c) provides for the completion of research on the sex-based class.

This last requirement, in section 2(d), requires the completion of the research investigation necessary to determine the effects, if any, of a hazardous substance or condition on the class not currently affected by the employer/contractor's policy. For example, if scientific evidence has been compiled only as to the hazardous reproductive effects of a substance on women, appropriate studies must be done to determine if any reproductive hazards exist for men. It is the position of the enforcement agencies that the time provided in section 2(d) is sufficient for employer/contractors to investigate, initiate and/or complete any scientific research regarding the harmful effects of a particular reproductive hazard on both sexes. In consultation with OSHA, the National Institute of Occupational Safety and Health and the National Institute of Environmental Health Safety, it was determined that such research could be performed in one year or less. Should preliminary research be needed to develop the appropriate protocol (method of exposure, dosage, etc.) a few additional months might be necessary. A specific period was specified as the shortest feasible time not to exceed two years, to allow for unforeseeable delays in the research process.

Sections 3(b)(1) and 3(b)(3) are intended to acknowledge the problems a small employer/contractor might have in completing the requisite research individually. Most of the complaints and information received by the enforcement agencies to date involve larger employers and contractors. The enforcement agencies are interested in [illegible]

[1] *McDonnell Douglas Corp.* v. *Green*, 411 U.S. 792 (1973).

[2] *Griggs* v. *Duke Power Company*, 401 U.S. 424 (1971); *Robinson* v. *Lorillard Co.*, 44 F. 2d 791 (4th Cir. 1971); *Albemarle Paper Company* v. *Moody*, 422 U.S. 407 (1975); *Uniform Guidelines on Employee Selection Procedures* (1978), 41 CFR Part 60–3.

comments on the extent of the use of hazardous substances and conditions in small employer/contractor's workplaces, on the number of exclusionary policies, practices and plans due to Section 3(b), and on the burdens that would be placed on small employers and contractors from compliance with the research requirements of sections 3(b) and 3(b)(2). Should a small employer/contractor be unable to initiate and complete the required research individually, the guidelines provide two alternatives. The small employer/contractor can, and in fact is encouraged, to conduct the research with one or more other employer/contractors and/or through a trade association. The requirements of sections 3(b)(2) and 3(c) will apply to such research. The small employer/contractor can also request, within the time period required by section 3(b), OSHA to perform the necessary research. OSHA is prepared to act promptly to such requests for assistance. In determining whether an employer has the necessary capacity, the enforcement agencies will consider such factors as whether the employer has the facilities and personnel to perform the scientific research required; whether the employer in the course of its business performs scientific research similar to that required; whether the employer has the resources, either by itself or jointly with other employers, to sponsor or contract out for the necessary research; and whether the employer routinely sponsors or contracts out for scientific research. An approved request will satisfy the requirements of section 3(b)(2).

Section 3 will be applicable only during the interim period while an employer/contractor is completing the necessary research (either individually or jointly or OSHA is completing the study for it. After that time all employment policies related to reproductive hazards must be in full compliance with the proposed guidelines.

Two final points should be noted. First, the *bona fide* occupational qualification exception does not apply to the situations covered by these guidelines. That narrow exception pertains only to situations where all or substantially all of a protected class is unable to perform the duties of the job in question. Such cannot be the case in the reproductive hazards setting, where exclusions are based on the premise of danger to the employee or fetus and not on the ability to perform.

Finally, these guidelines do not preclude an employer/contractor from temporarily removing employees of both sexes from work areas with reproductive hazards if such employees declare to the employer/contractor an intention to procreate and voluntarily request such exclusion. In advising employees of the potential risks posed by particular hazards, the employer/contractor shall do so on a non-discriminatory basis.

Signed at Washington, D.C. this 29th day of January, 1980.

Ray Marshall,

Secretary of Labor.

Eleanor Holmes Norton,

Chair For the Commission.

Donald Elisburg,

Assistant Secretary, Employment Standards Administration.

Weldon J. Rougeau,

Director, OFCCP.

It is contemplated that these guidelines, if adopted, would become a portion of 41 CFR Part 60–20 and would be added to 29 CFR Chapter XIV as a new Part 1603.

Interpretive Guidelines on Employment Discrimination and Reproductive Hazards

Sec. 1. *General requirements.* An employer/contractor whose work environment involves employee exposure to reproductive hazards shall not discriminate on the basis of sex (including pregnancy or childbearing capacity[1]) in hiring, work assignment, or other conditions of employment.

Sec. 2. *Nondiscriminatory policy to protect employees from reproductive hazards.* (a) An employer/contractor may not have policies, practices or plans designed to protect employees from reproductive hazards which, by their terms, exclude applicants or employees from employment opportunities on the basis of sex. Such policies are discriminatory on their face.

(b) An employer/contractor may not disparately treat individual applicants or employees on the basis of sex. Such treatment constitutes an apparent violation of Title VII and Executive Order No. 11246, as amended (Executive Order No. 11246).

(c) An employer/contractor may establish a neutral policy, practice or plan to protect all its employees from reproductive hazards. However, a facially neutral policy, practice or plan which has an adverse impact on one sex must be justified in accordance with relevant legal principles.[2]

(d) In determining whether an employer/contractor's conduct adversely affecting employment opportunities is non-discriminatory or justified pursuant to these guidelines, the following factors are among those which may be considered by the Equal Employment Opportunity Commission and the Office of Federal Contract Compliance Programs (hereinafter "the enforcement agencies"), where relevant:

(1) Whether the reproductive hazards policy, practice or plan is applied consistently to employees and applicants of both sexes, and to all scientifically recognized reproductive hazards in each of the employer/contractor's workplaces;

(2) Whether information obtained from the Occupational Safety and Health Administration (OSHA) or other federal, state or local authorities shows that the employer/contractor has complied with applicable occupational safety and health laws;

(3) Whether the employer/contractor has investigated the effects of all scientifically recognized reproductive hazards present in its workplaces not only on those classes adversely affected by the policy, practice or plan, but also on those relevant classes not adversely affected, and has relied upon reputable scientific evidence in developing its policy, practice or plan;

(4) Whether, with respect to any hazard for which the employer/contractor has an exclusionary policy, practice or plan, the hazard is significantly greater for or confined to the class excluded than for the class not excluded;

(5) Whether, prior to the institution of the reproductive hazard policy, practice or plan, the employer/contractor had provided the adversely affected sex with equal employment opportunities;

(6) Whether the class adversely affected by the policy, practice or plan in question is narrowly tailored to the type of hazard posed (overbroad policies, such as those which exclude all fertile women because of concern for possible harm to a fetus, are impermissible);

(7) Whether, with respect to any reproductive hazard for which the employer/contractor takes action resulting in exclusion of a sex-based class, there is no evidence that the hazard poses a significant health risk to body systems other than the

[1] Pregnancy Discrimination Act, Pub L. 95–555, 92 Stat. 2076 (1978). See Sec. 701 k of Title VII.

[2] *Griggs v. Duke Power Company*, 401 U.S. 424 (1971); see *Uniform Guidelines on Employee Selection Procedures* (1978), 41 CFR Part 60–3.

reproductive system for the class not excluded;

(8) Whether the employer/contractor has investigated alternatives to the exclusion of adversely affected employees from the workplace and, where feasible, adopted alternative means of protecting the affected employees from the reproductive hazard in question:

(i) Examples of such alternatives may include reduction of the level of exposure to the hazard so that the reproductive risk is minimized or eliminated; use of respirators or other protective devices to minimize exposure; product substitution; and transfer of affected employees, without loss of pay or other employment benefits and with continued accrual of seniority, to an area of the workplace in which exposure to the reproductive hazard is minimal or nonexistent;

(ii) In selecting from a group of alternatives, the employer/contractor shall select the alternative which has the least adverse impact upon the affected employees. In addition, whenever an employer/contractor is shown an alternative to the exclusionary policy, practice, or plan, or an alternative means of operating the business which has a lesser discriminatory impact, the employer/contractor must investigate the appropriateness of using the alternative.[3]

(iii) The employer/contractor, as part of the data supplied to the enforcement agencies, shall include an evaluation of the alternatives investigated;

(iv) There is a presumption that an employer/contractor who is not in compliance with occupational safety and health laws relating to the hazardous substance or condition has not considered all available alternatives to exclusion. This includes all applicable OSHA standards, and all obligations imposed by section 5(a)(1) of the Occupational Safety and Health Act;

(v) The enforcement agencies will consult with OSHA and others, as appropriate, on the relevant alternatives available in each particular situation;

(9) Whether the employer/contractor is monitoring scientific research and technological developments which may affect the appropriateness of its policy.

(e) Any evidence required by the enforcement agencies to show that an employer/contractor's conduct is non-discriminatory or justified pursuant to section 2(d) above must be made available by the employer/contractor to the enforcement agencies. The scientific evidence must be applicable to the conditions in the employer/contractor's workplace where the particular substance is used.

Sec. 3. *Temporary emergency exclusion.* There may be situations where an employer/contractor has obtained reputable scientific evidence that a workplace hazard causes or is likely to cause significant harm to the reproductive health of employees of one sex only, or of pregnant employees, and also where there is insufficient reputable scientific evidence concerning the reproductive harm to the other employees.

(a) In such situations, the employer/contractor may, as a temporary emergency measure, exclude susceptible applicants and remove endangered employees form the hazardous area provided the employer/contractor meets the following conditions:

(1) It has thoroughly searched the existing scientific evidence and the search reveals no reputable scientific evidence sufficient to suggest that the reproductive hazard might have a significant harmful effect on the reproductive health of employees not excluded by the policy in question.

(2) It has narrowly tailored its policy to limit any exclusionary impact solely to the group of employees or applicants endangered (see paragraph 2(d)(b).

(3) It has investigated and adopted suitable alternatives (see paragraph 2(d)(8).

(b) In addition to the conditions required under section 3(a)(1)–(3), within 6 months of the effective date of these guidelines, the employer/contractor with an exclusionary policy, practice or plan in existence on or before the date of these guidelines must initiate research designed to produce evidence of the effect of the reproductive hazard as used in the employer/contractor's workplace on the class not excluded. The employer/contractor developing such a policy, practice or plan after the effective date of these guidelines must initiate such research within six months of the implementation of the policy, practice or plan.

(1) If the employer/contractor does not have the capacity to conduct or sponsor the necessary research, OSHA will be available to facilitate this research on request. Such a request for assistance should be addressed to: Director, Office of Legislative and Inter-Agency Programs, Occupational Safety and Health Administration, Department of Labor, 200 Constitution Ave., NW., N-3623, Washington, D.C., 20210. An approved request for assistance is sufficient to bring such an employer/contractor into compliance with the requirement in Section 3(b) above as long as the employer/contractor subsequently cooperates with OSHA.

(2) All such research must be conducted according to accepted scientific methods. The study must be conducted in a manner designed to produce the data on the class not excluded in the shortest feasible time, not to exceed two years, from the date the study was begun. An extension will be granted only where the employer/contractor can show that, despite good faith efforts, circumstances beyond its control prevented completion within the required time.

(3) Employers/contractors are encouraged to sponsor or participate in these studies jointly. Such studies may satisfy the requirements of sections 3(b) and 3(b)(2).

(c) The scientific evidence necessary to meet the requirements of sections 3(a) and 3(b) must be applicable to the conditions in the employer/contractor's workplace where the particular substance is used.

(d) The enforcement agencies will not take enforcement action pursuant to these guidelines against an employer/contractor who meets the requirements set forth in section 3(a) and who meets the time frames established by section 3(b). However, this will not preclude the enforcement agencies from pursuing their administrative processes during the investigation of a charge or conduct of a compliance review, and does not relieve an employer/contractor from complying with any appropriate administrative and investigative processes.

(e) In any enforcement action brought by the enforcement agencies subsequent to the date by which an employer/contractor must have scientific research completed as required in section 3(b), no compensation for backpay will be sought for the interim period as long as the employer/contractor has complied with the conditions in Sections 3(a) and 3(b).

Sec. 4. *Requirements for employer/contractors with reputable scientific evidence.* Where the search conducted pursuant to section 3(a)(1) above reveals reputable scientific evidence or where the employer/contractor has reputable scientific evidence that the reproductive hazard does not have a significant harmful effect on the reproductive health of employees not excluded, and the employer/contractor meets the conditions set forth in sections 3(a)(2) and 3(a)(3) above, then the employer/contractor need not satisfy the conditions of section 3(b).

Authority: E.O. 11246, as amended and Title VII of the Civil Rights Act of 1964, as amended.

[FR Doc. 80-3510 Filed 1-31-80; 8:45 am]

BILLING CODE 6570-06-M

[3] *Albermarle Paper Company* v. *Moody*, 422 U.S. 407 (1975); *Robinson* v. *Lorillard Corporation*, 444 F. 2d 791 (4th Cir. 1971).

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FILE RA 10
1 Discussion 3 Handling
2 Comments 4 Information
Action Deadline

RO

Jerry W. Ross AT Houston

O

M. P. Breaux	AT	2430 1HC
R. L. Gibson, M.D.		1600 2HC
C. Wen, M.D.		833 GB
C. H. Bowman		2460 2HC
J. Fitzpatrick		Philadelphia
J. R. Strausser ✓		4013 2HC
T. B. Searcy		1552 WB
D. O. Cantrell		2438 1HC

Re: Exposure of Fertile Females to Teratogenic Substances in the Work Place

At the March Epidemiology Subcommittee Meeting, the issue of exposing fertile females to teratogenic substances in the work place was discussed. Gulf Policy 309 outlines the basic management decision of how such situations shall be handled. For purposes of implementing Gulf Policy 309, I offered to review the legal implications of barring fertile females from work areas where teratogenic substances are found.

Attached is a memorandum by John Nation, a law clerk in this department, who researched the subject issue. John indicates that there is a court-made exception to Title VII of the Civil Rights Act of 1974 which is commonly known as the Business Necessity Rule. It appears that under the Business Necessity Rule, Gulf may have a ligitimate defense to an EEOC suit resulting from Gulf's decision to bar fertile females from work areas where teratogenic substances occur above threshold levels.

This Business Necessity Rule exception appears to be the law in those areas where the technology does not exist to abate the teratogenic exposure. An example would be at GOCHEM's St. James' facility where fertile females have been barred from working inside the plant due to benzene exposure. At St. James the risk of benzene exposure from upsets and equipment malfunctions is such that 1) it creates a ligitimate risk to any unborn fetus of a female employee and 2) is not a circumstance for which the technology exists to abate the risk.

In those situations where the risk of teratogenic exposure to fertile females can be abated through the installation of abatement equipment, there may be a legal obligation to install such abatement equipment as opposed to barring fertile females from the work area. I would suspect that such obligation would depend on a large number of circumstances and conditions such as: cost of the abatement equipment, the number of employees involved, etc. Gulf Policy 309 reflects a management decision to install such abatement equipment where installation is technically and economically achievable.

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Hopefully, John's memorandum will be of some assistance in implementing Policy 309 and understanding its legal implications. If you have any questions, please contact me.

Jerry W. Ross

JWR/djh
Enclosure

FROM John D. Nation AT Houston

IN REPLY REFER TO

TO Jerry W. Ross AT

DATE April 23, 1979

Re: Epidemiology Subcommittee Report

EEOC IMPLICATIONS OF SEGREGATING FERTILE FEMALES FROM WORK AREAS INVOLVING USE OF TERATOGENIC SUBSTANCES

Gulf Policy 309 (rev. June 1, 1977), Occupational Exposure to Toxic Substances, reads as follows:

POLICY

Gulf will use all feasible measures to prevent exposure of its employees in the ordinary course of employment to any known toxic substances or harmful physical agents which may have a deleterious effect on employee health or well being.

PROCEDURE

1. The Gulf Medical and Health Resources Division of GS&T shall identify chemical, physical and biological agents that elicit a teratogenic, mutagenic, carcinogenic or highly toxic effect. This Division shall determine the degree of hazard and recommend threshold limits of exposure.

4.a. Gulf will not knowingly permit a pregnant female to work in an area where there is medically substantiated exposure to substances hazardous to the fetus, and will require any female working in such areas to report any

suspicion of pregnancy immediately to the Company through the local Medical Representative. Removal of a pregnant female from the work place because of the presence of hazardous agents will be in accordance with the Maternity Leave Policy #265 in the Human Resources Manual.

c. Where the development of such protective equipment, warning systems or engineering controls is not technically or economically feasible, Gulf will not employ fertile women for work in areas where teratogenic exposure is probable and significant exposure is possible, because teratogenic exposure creates hazards to the fetus during the early period of pregnancy, when a female may not know she is pregnant and thus may not be able to protect the fetus from exposure to the harmful substances.

There is some concern in implementing this policy that Gulf might be caught between a "rock and a hard place"; specifically its need to protect employees from toxic substances and its equal employment responsibilities. It is believed that should any employment discrimination suit be brought. Gulf would have a good line of defense under the "business necessity" exception to Title VII of the Civil Rights Act of 1974.

42 U.S.C. § 2000e (2)(a)(1),(2)(1976) provides:

> (a) Employers. It shall be an unlawful employment practice for an employer--

> (1) to fail or refuse to hire or to discharge any individual, or otherwise to discriminate against any individual with respect to his compensation, terms, conditions, or privileges of employment, because of such individual's race, color, religion, sex, or national origin; or
>
> (2) to limit, segregate, or classify his employees or applicants for employment in any way which would deprive or tend to deprive any individual of employment opportunities or otherwise adversly affect his status as an employee, because of such individual's race, color, religion, sex, or national origin.

There is a court-made exception to this provision, applicable to both racial and sexual discrimination suits, commonly known as the business necessity rule. Briefly, this rule states that an admittedly discriminatory employment practice will nevertheless be upheld by the courts if it is necessary to the safe and efficient operation of the employer's business.

As developed by the courts in cases such as Robinson v. Lorillard Corp., 444 F.2d 791 (4th Cir. 1971), cert. dism'd, 404 U.S. 1006 (1971), the rule has emerged with three basic requirements:

1) the business purpose must be sufficiently compelling to override any sexual impact;

2) the challenged practice must effectively carry out the business purpose it was designed to serve; and

3) there must be available no acceptable alternative practices or policies which would accomplish the business purpose advanced, or accomplish it equally well with a lesser differential sexual impact.

Very few challenged employers have used this doctrine as anything other than a dilatory defense. Most simply throw up the defense without attempting to develop a case under it. Yet in one case, an employer has carefully developed his case and squarely prevailed under the safety prong of the business necessity rule.

In Boyd v. Ozark Airlines, Inc., 419 F. Supp. 1061 (E.D. Mo. 1976), aff'd 568 F.2d 50 (8th Cir. 1977), Ozark had a minimum height requirement of 5'7" for pilots. Plaintiff, a trained female pilot, was only 5'2". The court agreed with the plaintiff that the practice was prima facie discriminatory. Thereupon, Ozark set up the business necessity defense. Ozark pointed out that the cockpits of its airliners were designed around a design eye reference point. When a pilot was seated so that his eyes were in this reference point, he would have the ability to see over the glare shield of the plane and still be able to view and reach all the controls. Should the pilot sit below the reference point, the changed angle of vision could cause a distorted vision of the ground below, causing landing difficulties.

Ozark tested the plaintiff in the cockpits of both its plane types, the FH227 and the DC-9. When seated at the design eye reference point, she was unable fully to rotate the wheel in one, and could rotate the other only barely, with less the minimum safe rate of clearance between body and wheel. The court said that the evidence clearly indicated

that plaintiff at a height of 5'2" could not safely fly Ozark's aircraft. (The company was, however, ordered to lower the height requirements to 5'5").

Applying the doctrine to the present situation, Gulf should easily be able to show that the necessity for separating fertile females from teratogenic substances is sufficiently compelling to override the sexual impact. It is also evident that the practice carries out the business purpose of maintaining employee safety. In determining whether an employment practice is justified by the business necessity rule, it is significant to note that the courts will look to methods used by other similar companies in dealing with the same problem. In Boyd, the court looked to minimum height requirements as established by other carriers such as American, Continental, Delta and the military. Their height requirements were in substantial accord with Ozark's.

Similarly, Gulf should be able to show that other companies who use teratogens follow the same practice. In a hearing before the National Safety Congress on October 3, 1978 (reported in OSHA REPORTER, October 5, 1978 pp. 569-70), Richard L. O'Connell, Director of Corporate Health Affairs and Leonard Krause, Director of Environment Hygiene and Toxicology for Olin Corporation outlined Olin Company policy on exposure to teratogens. Krause testified that Olin segregates fertile women from areas where there will be substantial contact with known or suspected teratogens.

Where work will involve only limited exposure, Olin allows females to work in such areas after the signing of a waiver. Thus, it should be easy for Gulf to show the hazard and the necessity for segregation.

The third prong of the test requires further analysis. Gulf must be able to show that there are no alternative policies which would accomplish the same result with a lesser discriminatory impact. The logical interpretation of this is that Gulf must show that there is absolutely no alternative to refusing to hire fertile women in workplaces involving teratogens. However, in its search for alternative policies, a court might inquire whether the nuisance can be abated. If, for instance, it is possible and feasible to remove the teratogens, or develop protective and/or warning systems, a court might hold that the company has not satisfied the third prong of the business necessity rule. If, however, exposure to teratogens cannot be eliminated and warning and protective systems are not technically or economically feasible, a court would probably decide that there is no alternative to segregating fertile females from teratogenic exposure. No court, however, has undertaken this kind of analysis. The Boyd court noted that Ozark had no control over the specifications and design of the cockpits of their aircraft, but it is not clear whether the court would have required Ozark to change the design in order to accommodate shorter pilots had it been in their power to do so.

In conclusion, it must be emphasized that there is little law respecting equal employment implications of segregating fertile women from workplaces involving teratogenic exposure. Leon J. Warshaw, speaking at the same National Safety Congress, argued that a definitive solution to this problem does not exist, and that the only alternative route is through compromise among industry, labor and the EEOC. What form any compromise would entail and what guidelines will be issued by EEOC are unclear. However, should an employment discrimination suit be brought, Gulf should have enough material to build a sound defense under the business necessity exception to Title VII.

John D. Nation

JDN:map

final standard and therefore is too low, Deakins told the court. A "conservative estimate" would be at least $1 billion, he added. A stay is necessary because substantial sums would have to be committed soon to meet the final deadline of September 1982, according to Deakins.

Dennis Kade, of the office of the Solicitor of Labor, disputed the industry's contention that substantial expenditures must be made in the near future. Kade noted that initial monitoring of exposure levels need not be completed until March 1979, and suggested that orders for control equipment could not be placed before then. In response to a question from the court, Kade stated that DOL would have no objection to an expedited review proceeding.

Jeremiah Collins a Washington, D.C. attorney, speaking for union intervenors, assured the court that employees in the textile industry are willing to wear respirators when necessary.

The arguments were heard by Circuit Judges H. Emory Widener, John D. Butzner, Jr., and Kenneth K. Hall. Judge Widener dissented from the order of transfer.

Litigation

DOL CANNOT GIVE MANDATORY EFFECT TO ADVISORY CRANE RULE, COURT RULES

The Secretary of Labor exceeded statutory authority by giving mandatory effect to a standard derived from an advisory private rule on cranes, according to the U.S. Court of Appeals for the Third Circuit.

The court, in *Marshall v. Pittsburgh-Des Moines Steel Company and OSAHRC* (No. 77-1809) and *Marshall v. Wheeling-Pittsburgh Steel Corporation, Wheeling Corrugating Company, and OSAHRC* (No. 77-1810), held that the guarding requirements of 29 CFR 1910.179(e)(6)(i) and (g)(2)(i) are merely advisory for cranes constructed before August 31, 1979. The Occupational Safety and Health Review Commission had reached the same conclusion (5 OSHC 1420 and 1495).

The secretary promulgated the crane standard as a "national consensus standard" under Section 6(a) of the Occupational Safety and Health Act. The Labor Department regulation, in a general subsection on applicability, says that cranes constructed and installed after August 31, 1971, "shall" meet the design specifications of the American National Standard Safety Code for Overhead and Gantry Cranes (ANSI B30.2.0-1967). Cranes constructed before that date, on the other hand, "should" be modified, according to 29 CFR 1910.179(b)(2).

The court agreed with the Labor Department that the regulation was intended to be mandatory in its entirety. When first promulgated, it used the term "shall." The secretary stated that changes made in a revision 10 weeks later — including the change back to "should," the term used in the American National Standards Institute standard — were not intended to be substantive.

The court held, however, that Section 6(a) of the Act did not authorize the secretary to give mandatory effect to the advisory portion of the ANSI rule. Such a change would have been proper only if Section 6(b) rulemaking procedures were followed, the court said. "The overriding ameliorative goals of the statute cannot justify circumvention of its procedural requirements, the court concluded.

The Labor Department also urged that the subsections on guarding of parts and equipment were enforceable in their own right, although they were derived from the ANSI safety code. The general subsection, whether advisory or mandatory, was irrelevant because the guarding requirements were concerned with construction and installation and not with the crane's basic design, the Government said.

The court responded that the ANSI code, the source of the subsection on applicability, was not limited to design-oriented standards. That code's introduction used the term "rules" rather than "design specifications." The court also said that it was relying on the "plain wording of the standard" in finding the guarding requirements to be design specifications.

Chief Judge Collins J. Seitz wrote the opinion. He was joined by Senior Circuit Judge Francis L. VanDusen and Circuit Judge Max Rosenn. The decision will appear in a future Decisions supplement.

Cotton Dust

AGRICULTURE APPROPRIATIONS APPROVED; $100,000 INCLUDED TO STUDY OSHA RULE

The conference committee's report on the Department of Agriculture appropriations for fiscal 1979, which includes a provision for a study of the Occupational Safety and Health Administration's cotton dust standard, was approved September 26 by the House and September 27 by the Senate.

The Senate originally approved $200,000 to fund a National Academy of Sciences study to review OSHA's cotton dust standards (29 CFR 1910.1043 and 1910.1046) which were issued June 23 (Current Report, August 17, p. 382).

The report of the conference committee, which resolved differences between the House and Senate versions of the bill, stated that the conferees fully supported the need for such a study, but they said that $100,000 is the most such a study will cost.

The bill has been sent to the White House and is awaiting action by the President.

Health Hazards

RIGHTS, PROTECTION FOR PREGNANT WOMEN IN WORKPLACE OUTLINED AT SAFETY CONGRESS

CHICAGO ILL. — (By an OSHR Staff correspondent) — Exclusion of women of childbearing age from potentially hazardous work situations that may affect reproductive capacity will not solve the problem of protecting the rights of women in the workplace, the National Safety Congress was told October 3.

Leon J. Warshaw, vice president and corporate medical director, Equitable Life Assurance Society of the U.S., declared that a definitive solution does not exist to the problem of health hazards affecting pregnant women in the workplace. However, he outlined some "acceptable compromises" for industry, labor, equal opportunity officials, and the women themselves.

Warshaw explained that there are some jobs that the pregnant woman cannot perform and others that she should not attempt because of potential hazards to herself or to her unborn child. Normal women are no more susceptible to workplace hazards than their male counterparts, he said, but "pregnancy changes this."

The ideal would be to make the workplace safe for all workers, Warshaw declared, but this is not possible for many reasons including technical constraints and prohibitive cost. Some problems of health hazards of women of

childbearing age involve exclusion from some jobs, retention of the pay rate at the new job, seniority protection, discrimination claims, and the right to privacy.

Decisions are needed on a case-by-case basis, Warshaw said, with the debate and discussion to include management, labor, women's rights groups, and the employee herself. He recommended an industry policy which would provide that:

- The health of the worker and her unborn child be given prime consideration.
- The employee be given the best professional advice on family planning and prenatal care.
- A system be established to provide workers with information on potential workplace hazards and guidelines provided to help employees make decisions regarding the continuation of such work.
- An educational program be established for females of childbearing capacity to avoid or control hazards in their personal lives such as drugs, alcohol, smoking, and exposure to household chemicals.
- Research be conducted on new chemical and possible mutagenic effects, with the results of such research divulged to those who may have been exposed and the right of the worker to that information to outweigh consideration of trade secrets.
- Companies and unions endorse a code of ethics for health in the workplace, and insist that all health professionals conform to its precepts.

All of this is "eminently possible" if industry hires proper professionals and unions emphasize the health of the workers, Warshaw explained. He called for honesty, dignity, equality, and compassionate treatment of female workers and their male counterparts.

Richard L. O'Connell, director of corporate health affairs, Olin Corporation, Stanford, Conn., declared that women belong in the workplace, but he urged industry to recognize that there are unique needs and characteristics of women that must be accommodated.

He outlined the physical changes which take place in pregnant women and listed possible problems of pregnancy which could be the results of workplace situations or which could affect a female's performance on the job. He warned that there are some substances in the workplace that could lead to miscarriages.

O'Connell also cited teratogenicity problems and explained that these involve whatever interrupts the fetal growth process. Chemicals recognized by the National Institute for Occupational Safety and Health as teratogens, O'Connell said, include cadmium, carbaryl, carbontetrachloride, chromium compound, 4—dimethylaminozobenzene, formaldehyde, lead, mercury, oxides of nitrogen, paraquat, and parathion. He cautioned against "panic" regarding other lists and possible effects from other substances until they are proven teratogens.

Leonard Krause, director of environmental hygiene and toxicology, Olin Corporation, New Haven, Conn., described his company's policy regarding women of childbearing age in the workplace. He said the problem must be addressed as more women between the ages of 16 and 45 enter the workforce and as more hazards are recognized that may affect them.

Krause explained that Olin's policy involves ongoing evaluation of each case of possible hazards to employees. There are three categories for placement of women of childbearing age within the company he said. The first is the restricted category where work may require contact and exposure to known or suspected agents which could harm women of childbearing age. Such women are prohibited from working these restricted areas.

A "controlled category" involves limited contact where discretion is allowed. Women may work in such areas but sign a form to show that they have read a guide on prenatal chemical or physical exposure in such controlled areas.

The third category is for the unrestricted area in which exposure does not constitute a hazard, Krause said.

Corporate industrial hygienists and toxicology departments should analyze each job, determine to which classification the employees would belong, Krause explained, and specify limitations for females of childbearing age.

Cotton Dust

CARTER DEFENDS PROPOSED STANDARD AS "REASONABLE" BEFORE THE NAFB

President Carter defended his proposed cotton dust standards September 29 in an interview with the National Association of Farm Broadcasters held in Washington, D.C.

Answering a charge that the proposed standards will "close down" segments of the cotton industry, Carter stated that the regulations, which would lower the permissible level of airborne cotton dust in mills and textile plants, are "reasonable."

He further asserted that the standards and method of enforcement advocated by the previous administration would have cost industry an estimated $2.7 billion, while the ones issued by the Labor Department September 4 had cut that cost substantially, perhaps to one-fourth.

Carter expressed his belief that, although the regulations currently are being challenged by the National Cotton Council, the "courts will rule in favor" of the standards.

The Senate recently voted to suspend the new regulations until May 1 in an amendment to the appropriations bill for the Departments of Labor and Health, Education, and Welfare.

Asbestos

BALTIMORE SHIP WORKERS TO BE STUDIED BY MOUNT SINAI MEDICAL CENTER TEAM

A union local representing workers at two Bethlehem Steel shipyards in Baltimore has arranged with the Mount Sinai Medical Center of New York to conduct an occupational disease study of present and retired workers.

Bob Pemberton, business agent for Local 24, Industrial Union of Marine and Shipbuilding Workers of America (AFL-CIO), said the membership, numbering about 1,700 had approved the agreement for the study by Mount Sinai, expected to get under way within a few weeks.

Pemberton said the members hoped that "if there is something we can do to help prevent disease for the people who are working here now," the study would find it.

While asbestos-related disease will be one health effect looked for, Pemberton said, comprehensive medical examinations will be given to present and former ship workers to discover any type of occupational disease patterns.

Individual test results will be given to each worker who is examined, Pemberton said, but these findings will not be seen by the union, as the agreement stated. The union will see overall statistical results but not the individual identities of workers, according to Pemberton.

The statistics will be used to identify health effects by crafts within the local. Some of the crafts at the Bethlehem facilities are boilermakers, firemen, sandblasters, blacksmiths, carpenters, and joiners.

The following is a commentary on those issues surrounding women in the workplace. Three significant trends have led us to our present discussions, with a call for more research into the reproductive effects of chemical and physical agents.

Women in the workplace, the issues

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introduction

The following information is not being offered as legal interpretation or legal advice but rather it is information which should be of some aid when discussions arise regarding women in the workplace.

The exposure of women of childbearing age to potentially harmful agents has recently received a great deal of attention among health professionals and the general public. This has generated a host of medical, legal, and social issues, many of which are still unresolved.

discussion

It has been mandated by legislation that the female adult has the right to employment in those occupations that were formerly only occupied by the male adult. Out of concern for the health of the individual female adult and her offspring, many employers have adopted exclusionary policies for women of the childbearing age. This has been interpreted as a threat to women's recent progress towards equal footing with men in the area of employment.

It has been suggested that three noteworthy trends have led us to those discussions and issues that surround our present subject at hand. These trends are as follows:[1]

- The shift of women to employment outside the home
- The social objective of equal employment opportunity
- The social objective of safe and healthful workplaces and concomitant knowledge about environmental health hazards

Implementation of the objectives has led to the passage of regulations and laws which may be interpreted as being conflicting. A close examination of the subject at hand will reveal the dependence of society upon the interelationship of law and science to resolve conflicts and issues that may arise. In this case, one may be outdistancing the other. It is generally conceded that at the present time science does not have sufficient answers to existing and arising questions concerning the effects chemical and physical agents may or may not have upon the reproductive process of both men and women.

With that, let's examine the first trend on our list, the shift of women to employment outside the home. The changing pattern of employment of women over the last 50 years reflects a basic transformation in American life, precipitated by a variety of reasons.

The growth in numbers of women in the workforce is becoming significantly greater with the passage of time. The number of women employed, on an average annual monthly basis during 1978 was approximately 42 million, 32 million of whom were full-time. Therefore, out of a total workforce of 100 million individuals, women comprise 42 percent. Of those 42 million women in the workforce, approximately 30 million or 71 percent are of childbearing age (16–44 years). Using a fertility rate of 67.8 live births per 1000,women reveals a possibility of 2 million pregnancies to those employed in any recent year. In addition, approximatley 3 million of those women, of childbearing age, are employed in industries where exposure to a reproductive hazard may possibly occur.[2]

Obviously not all women of childbearing age face the same risk. Men and women having current reproductive capacity may choose not to exercise it, be practicing birth control, or postponing with the desire to conceive in the future. Additionally, there are those without reproductive capacity due to age, injury, illness or surgery. Therefore, the possibility of 2 million pregnancies may be significantly exaggerated.

The second significant trend or social objective, namely equal employment opportunity, has spawned a continuous stream of enacted statutes with concurrent interpretations. The most significant of these statutes is Title VII of the Civil Rights Act of 1964 as amended by the Equal Employment Opportunity Act of 1972. In addition, Executive Order No. 11375 not only prohibits discrimination by Federal Contractors but also mandates affirmative action. Enforcement of this order is administered by the Office of Federal Contract Compliance whereas enforcement of Title VII is through the Equal Employment Opportunity Commission. Just recently four Federal agencies, the Civil Service Commission, the Equal Employment Opportunity Commission, the Department of Labor, and the Department of Justice adopted the Uniform Guidelines on

Employee Selection Procedures of 1978 which are intended to establish a uniform Federal poshtion in the area of prohibiting discriminatory practices on grounds of race, color, religion, sex, or national origin.

The Guidelines are applicable to tests and other selection procedures which are used as a basis for any employment decision.

So as one can see, significant legislation has been enacted that nearly covers all aspects of discrimination relating to employment. However, interpretation and application of each appears to vary significantly depending upon the setting and locale.

As mentioned previously, Title VII of the Civil Rights Act appears to be the most significant statute enacted to date.

Sec. 703 of Title VII of the Civil Rights Act of 1964 as amended by the Equal Employment Opportunity Act of 1972 states:

A.) It shall be an unlawful employment practice for an employer –

1.) To fail or refuse to hire or to discharge any individual, or otherwise to discriminate against any individual with respect to his compensation, terms, conditions, or privileges of employment, because of such individuals . . . sex . . . or;

2.) To limit, segregate, or classify his employees or applicants for employment in any way which would deprive or tend to deprive any individual of employment opportunities or otherwise adversely affect his status as an employee, because of such individuals . . . sex . . .

Initially, Title VII of 1964 as enacted, applied only to private employers. At that time an employer was defined as a person engaged in an industry affecting commerce who had 25 or more employees for each working day in each of 20 or more calendar weeks in the current or preceding year.[3]

However, Title VII as amended by the Equal Employment Opportunities Act of 1972 reduced the number of employees needed for an employer to be covered to 15 and removed the exemption of state and local governments. Although the U.S. Government is not included under the definition of employer, it is still required to be made free of discrimination (Executive Order 11375).

Looking at the specifics of Title VII leads one to the interpretation that all classes of workers must be treated alike; no differential treatment is tolerated. The prohibition against sex discrimination requires employers to treat employees in a "sex blind fashion", *i.e.* elimination of such classifications as men's work vs. women's work.[4] Thus if an employer adopts an exclusionary policy for any class of worker it would appear that this would be a violation of Title VII.

Guidelines on discrimination because of sex have been published by the Equal Employment Opportunity Commission in CFR 29, Chapter XIV, Part 1604. The guidelines are basic interpretations of Title VII as related to sex discrimination and are applicable to cases and charges filed with the Commission. The Office of Federal Contract Compliance has also published similar guidelines in 41 CFR, Part 60-20.

Part 1604.3 (a) of the guidelines states as follows:

"It is an unlawful employment practice to classify a job as 'male or female' . . . accordingly, employment practices are unlawful which arbitrarily classify jobs so that:

1.) A female is prohibited from applying for a job labeled "male" or for a job in a "male" line of progression and vice versa.

In addition under the same section, Paragraph (b) also states:

"A seniority system or line of progression which distinguishes between a "light" or "heavy" job constitutes an unlawful employment practice if it operates as a disguised form of classification by sex, or creates unreasonable obstacles to the advancement by members of either sex into jobs which members of that sex would reasonably be expected to perform."

Although Title VII of the Civil Rights Act prohibits discrimination, an exception is offered by Sec. 703 (e) which states:

"It shall not be an unlawful employment practice for an employer to hire and employ employees . . . on the basis of . . . sex . . . in those certian instances where sex . . . is a bona fide occupational qualification reasonably necessary to the normal operation of that particular business or enterprise . . .

Again the E.E.O.C. Guidelines on sex discrimination provide the following interpretation:

"The Commission believes that the bona fide occupational qualification exception as to sex should be interpreted narrowly . . .

1.) "The Commission will find that the following situations do not warrant the application exceptions:"

i) "The refusal to hire a woman because of her sex based on assumptions of the comparative employment characteristics of women in general . . ."

ii) "The refusal to hire an individual based on stereotyped characterizations of the sexes . . . the principle of non-discrimination requires that individuals be considered on the basis of individual capacities and not on the basis of any characteristics generally attributed to the group."

Based upon the above guidelines, it is easy to assume that the application of a bona fide occupational qualification is very narrow indeed and use of it to provide relief from a

discrimination charge for exclusion of a given class of workers from a particular environment would be difficult. It's only application appears to be in areas of artistic endeavor as the following quote from the guidelines yield:

> *"Where it is necessary for the purpose of authenticity or genuineness, the Commission will consider sex to be a bona fide occupational qualification, e.g., an actor or actress"*

To date, according to the E.E.O.C., no bona fide occupational qualifications have been granted for an exclusionary policy regarding reproductive hazards. However, it is important to note that it was indicated that the B.F.O.Q. has not been tested under these circumstances.

The philosophy indicated by the O.F.C.C.P. and the E.E.O.C. regarding exclusionary policies is somewhat interesting. It was noted that if an employer maintains an exclusionary policy for a particular class, that employer must present scientific conclusive evidence that demonstrates, not only that the excluded class is exposed to a risk, but also that the unexcluded class is not exposed to the same or similar risk. In other words "a universally disproportionate risk exists."

Extrapolating this to a policy of excluding pregnant or fertile women would possibly indicate the following if in fact the above philosophy were to be enforced relating to Title VII.

1. *The employer would have to present scientific evidence that the substance has been conclusively identified as a teratogen, and*
2. *that conclusive scientific evidence has indicated that the substance is not a mutagen, carcinogen, gametotoxin; or does not cause sexual dysfunction.*

The above circumstance is only hypothetical, however, the important issue is that the teratogen classification indicates sex-specificity.

The above task would appear to be near impossible to attempt. The philosophy was only indicated and it was noted that guidelines on the subject may soon be published by these agencies.

At present it is estimated that 63,000 chemicals are in use,[5] the majority of which have not been investigated as to reproductive effects. Current standards addressing the problem are also lacking and, as mentioned previously, a close look at the issues involved reveals the interelationships of law and science.[6] It appears that in this particular situation one is out-distancing the other; current scientific information regarding reproductive effects has not routinely been addressed during the rulemaking process. However, recently some changes in the standard setting process have taken place regarding the issues at hand and with that let's look at the second social objective, safety and health.

Congress has delegated the responsibility of assuring safe and healthful working conditions for "working men and women" to the Occupational Safety and Health Administration within the Department of Labor.

Public Law 91-596, Section 6, Paragraph 5 yields the following provision for regulation of toxic substances:

> *"The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents . . ., shall set the standard, which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity . . ."*

It is important to note that the word feasible has specific limitations, most recent of which its definition has been implied to be of economic feasibility as a result of a Circuit Court decision on the Benzene Standard.

However, putting that aside, OSHA has put forth the following interpretation of both the Act and more specifically Section 6 as it relates to issues about reproductive hazards:

> *"At OSHA we are dedicated – and it is our legal responsibility – to assure so far as possible safe and healthful workplaces for all workers – men and women. And that includes protection of all functional capacities, including the reproductive capacity."*[7]

With this responsibility in mind, reproductive issues were of major significance in setting an acceptable lead standard. In fact, a great deal of testimony centered around the effects lead has upon the reproductive process of both men and women as the following quote yields:

> *"OSHA has concluded that damage to the fetus due to parental exposure to lead represents material impairment of the reproductive capacity of the parent involved"*[8]

The lead standard appears to be the first of its kind, in that in setting a permissible exposure level, the issue of reproductive functional capacity was paramount.

conclusion

If we are to close the gap between law and science in this particular area, then the need for information on the reproductive effects of the other 63,000 chemicals is very important indeed. If OSHA is to continue to maintain its current responsibility and/or interpretation of functional capacity which encompasses reproductive capacity, in setting those standards which assure safe and healthful working conditions for men and women, a new, possibly overdue emphasis upon the regulation of toxic substances may be on the horizon.

Overall, it would appear that a coordinated effort is necessary between those agencies responsible for administration of the social objectives that have been discussed here.

In closing, I would like to use the following quote of Dr. K.P. Russel;

> *"The obstetrical axiom that we are always dealing with two individuals rather than one is well known, but not always appreciated. For it is not the pregnant*

worker alone with which we should be concerned, but also the health of the unborne. To be well-borne should be the basic right of every fetus."

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Each manuscript receives at least two reviews, one by the reviewer and a verification review by the editorial advisor. Quite often, two reviewers are used on the initial review, plus the advisor's review. When a manuscript is judged in need of major revision and a second review, the revised work is evaluated by the same advisor and reviewer(s) who handled it initially. Third reviews are not uncommon.

Often, individuals express an interest in reviewing manuscripts. To broaden the scope of reviewer availability, we are calling for volunteers willing to review a reasonable number of submitted manuscripts annually. Identity of the reviewer is not revealed to the author without the reviewer's permission.

To volunteer, please write to the Editor, American Industrial Hygiene Association JOURNAL, 475 Wolf Ledges Parkway, Akron, OH 44311. In a one-page letter, state your interest in reviewing, your mailing address and business phone number. List your areas of expertise and interest, together with a brief summary of your experience and qualifications. All letters received will be duplicated and forwarded to the editorial advisors. When the need arises, they will contact the volunteer determined to be best suited to review the manuscript they are processing.

All interested are urged to submit a letter, as described above. A similar call for volunteers was made some time ago and a substantial number of replies were received. These went out to the advisors group serving at that time. Since then, a number of changes in the advisors roster have taken place.

So that we will have current information on file, even though you have volunteered in the past, submit a current letter of interest.

The first distribution of volunteer letters to the editorial advisors is planned for April 15, 1980. To be included, your letter must be received no later than April 7, 1980.

(conoco)

Interoffice Communication

To Plant Managers

From R. E. Lehmkuhl

Date October 31, 1979

Subject Guidelines for Employment in Chemical Plants

Attached is a copy of my letter dated August 27 and a copy of Dr. Lembke's letter of October 17 in reply.

If you have any questions concerning any part of the guidelines, please advise D. L. Norwood.

Please implement these employment guidelines immediately.

R. E. Lehmkuhl

wb

cc:

R. W. Gerwig - Stamford
J. D. Burns - Houston
J. J. Hall - Houston
D. L. Norwood - Houston
D. C. Bartlett - Houston
Flynt Kennedy - Ponca City
D. A. Kuhn - Houston
J. E. Landers - Stamford
R. L. Lembke, M. D. - Ponca City
L. C. Reed - Houston
S. E. Conly - Houston
D. E. Nicholson - Houston
T. D. Montgomery - Legal, Houston
M. A. Fisher - Legal, Houston

Interoffice Communication

To R. E. Lehmkuhl - Houston

Employee Rels

From Robert L. Lembke, M.D. - Ponca City

OCT 19 1979

Date October 17, 1979

Subject GUIDELINES FOR EMPLOYMENT IN CHEMICAL PLANTS

After receiving your interoffice communication on the above subject dated August 27, 1979, I read it carefully and then circulated it to the other physicians and industrial hygienists in the Medical Division for their information and for any comments which they might like to make regarding its contents. Just yesterday, the interoffice communication was returned to me because in the interim many of the physicians and industrial hygienists were away from the office on company business.

All of us concur that the guidelines as set forth by you are appropriate and none of us disapprove of any statements which you have made.

Robert L. Lembke, M.D.
Medical Director

jr
cc:
R. W. Gerwig, Stamford
J. D. Burns, Houston
D. A. Kuhn, Houston
D. L. Norwood, Houston
M. A. Fisher, Houston
T. D. Montgomery, Houston

Interoffice Communication

To R. L. Lembke, M.D., D. E. Nicholson

From R. E. Lehmkuhl

Date August 27, 1979

Subject GUIDELINES FOR EMPLOYMENT IN CHEMICAL PLANTS

Any comprehensive policy for employment of men and women in our chemical plants must be compatible with sometimes conflicting restraints. It must give workers ample protection from hazards in the workplace yet be non-discriminatory where there is no reason to employ one sex but not the other. The subject guidelines are believed to strike a balance that will satisfy both requirements even in plants where chemicals such as benzene or vinyl chloride are found. The policy is not without risk to employees or Conoco. Indeed, we cannot provide a "risk-free" workplace for anyone. We believe, however, that the policy satisfactorily balances the needs to provide ample employee protection, maintain equal opportunity and keep the risk of costly litigation for Conoco low.

Please review this program and determine if it represents an acceptable course for Conoco Chemicals.

POLICY

(1) Maintain the workplace in compliance or better with pertinent OSHA standards. Where OSHA standards do not exist, abide by industry consensus standards. When neither of these exist, establish Conoco standards, comply with them and exercise prudent control of all other chemicals.

(2) Explain in detail to each employee at the time of initial hire and on a regular basis thereafter:

(a) What chemicals are present in the workplace and the safe practices for working near and handling these chemicals;

(b) What information we have about the potential carcinogenic, mutagenic, teratogenic, and other health effects of any chemicals in the workplace, the levels at which these effects have been known to occur and the fact that we maintain our exposures below these levels.

(3) Assure that the safe practices are enforced.

(4) Employ anyone capable of performing the job satisfactorily without regard to sex, race, age, or other non-performance standard.

BENEFITS OF THESE GUIDELINES

(1) We maintain a workplace that amply protects the safety and health of <u>everyone</u>.

(2) We have a policy that responds properly to the requirements of occupational safety and health as well as equal opportunity.

(3) We are able to reach our goals of employing more women in our operations, especially female chemical engineers at entry level jobs for future assignments in management.

(4) We open up for our recruiting a larger resource base (women) where there are qualified candidates. Our success with this group may be better because other companies exclude them from consideration.

RISKS

If a claim is brought by a worker against the company for an alleged injury or illness when we are fully complying with OSHA, consensus or Conoco standards, it is likely that we would be liable for workmen's compensation alone and would not be susceptible to a negligence suit. On the other hand, the developing fetus is not a "worker" so presumably a malformed child could sue the company for putting him at an unacceptable risk in the workplace. Since there is no precedent for this kind of case, I cannot imagine what the outcome would be. However, considering the number of women in our employ, the number who will get pregnant, the known percentage of birth defects as well as the probability of suit, and the burden on the plaintiff to establish a causal link between the malformation and the parent's exposure to chemicals, the likelihood of such a suit is small. Further, while the risk of liability is not eliminated through this policy, our present policy does not eliminate the risk of such a suit on behalf of the deformed fetus as a result of the father's exposure to toxic chemicals.

R. E. Lehmkuhl

ajo

cc R. W. Gerwig - Stamford
J. D. Burns - Houston
D. A. Kuhn - Houston
D. L. Norwood - Houston
M. A. Fisher - Legal, Houston
T. D. Montgomery - Legal, Houston